REMARKS

This document is filed in reply to the Office Action dated September 7, 2005 ("Office Action"). Applicants have amended claims 1 and 2 to promote clarity. Support for the amendment to claim 1 can be found at page 3, lines 13-19 of the specification. Applicants have also amended claim 6 to delete two non-elected species and cancelled claim 12. No new matter has been introduced.

Claims 1-11, 13-18, and 21-38 are pending. Among them, non-elected claims 17-18 and 21-38 have been withdrawn and claims 1-11 and 13-16 are under examination. Reconsideration of this application is requested in view of the following remarks:

Species Election

The Examiner withdrew claims 5, 7-9, and 14 for being drawn to non-elected species. See the Office Action, page 3, lines 9-11. Applicants respectfully traverse.

In the Restriction Requirement dated October 4, 2004, the previous Examiner requested that a species be elected for examination from "those listed in Claim 6-9." See the Restriction Requirement, page 3, lines 4-9. In response to the request, Applicants elected one of the species listed in claim 6, i.e., an "antigen presenting cell (APC) targeting molecule ... derived from SPE-C." In view of this election, the present Examiner withdrew claims 5, 7-9, and 14. Applicants disagree.

According to the Restriction Requirement, claim 5 was not subjected to species election. Indeed, claim 5 merely specifies bacteria from which an APC targeting molecule is derived. Thus, claim 5 should not be withdrawn. Claims 7-9 and 14, dependent from claim 6, specify variants of the elected APC targeting molecule. As they are subsumed in claim 6, they should not be withdrawn in view of the species election. For the above remarks, Applicants respectfully request that claims 5, 7-9, and 14 be considered in this application.

Objection

The Examiner objected to the Preliminary Amendments dated March 13, 2002 and requested a marked-up version of the proposed amendments. See the Office Action, page 2, lines 14-15. Applicants have presented the marked-up version as requested.

Rejection under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1-4, 6, 10-13, and 15-16 for indefiniteness on three grounds. Applicants traverse each below.

I

Independent claim 1 or 2 covers an immunomodulator that contains an immunomodulatory antigen. The Examiner stated that the terms "immunomodulator" and "immunomodulatory [antigen]" recited in claim 1 or 2 are indefinite. According to her, the two terms are "ambiguous as the direction (positive or negative) or degree of said immunomodulator." See the Office Action, page 2, lines 25-27.

Applicants note that the specification teaches both the "direction" and "degree" of the immunomodulator or immunomodulatory antigen. For example, the specification teaches that, "depending on the primary sequence of the [antigen]," the immunomodulator can be used for "enhancing or suppressing a host immune response." See, e.g., page 1, lines 4-6 and page 7, lines 1- 11. Also, at page 6, last paragraph and, page 24, third paragraph, the specification teaches that the use for "improving immunogenicity" and the degree of improvement.

In this connection, Applicants would like to remind the Examiner that "[a] claim need not 'describe' the invention, such description being the role of the disclosure portion of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986). Also, "it is the function of the descriptive portion of the specification and not that of the claims to set forth operable proportions and similar process parameters and that claims are not rendered indefinite by the absence of the recitation of such limitations." *Ex parte Jackson*, 217 USPQ 804 (POBA 1982). Further, "[w]hether a claim is invalid for indefiniteness depends on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the Specification." *North American Vaccine Inc. v. American Cyanmid Co.*, 28 USPQ2d 1333 (Fed. Cir. 1993).

Here, the "direction (positive or negative) or degree of said immunomodulator" is just an operable proportion or a process parameter for claims 1 and 2. Accordingly, the claims are not rendered indefinite by the absence of its recitation. Also, "those skilled in the art," when reading claims 1 and 2 "in the light of the Specification," would recognize how the "immunomodulator"

and "immunomodulatory [antigen]" would modulate immune response and "understand the scope of" claims 1 and 2. Thus, claims 1 and 2 meet the definiteness requirement.

II

Independent claim 1 recites "a superantigen ... [that] does not include a fully functional T cell receptor binding site." Claim 2 recites "[an]... APC targeting molecule ... has little or no ability to activate T cells." According to the Examiner:

> the terms 'fully functional' in Claim 1 and 'little or no ability' in Claim 2 are relative terms which render the claims definite. The terms are not defined by the claim or the specification, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

See the Office Action, page 2, line 34 to page 3, lines -36.

Applicants disagree and note that "[t]he fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." See MPEP 2173.05(b).

Here, a superantigen, as recited in claim 1, is well known in the art. Indeed, well documented is its domain that binds to a functional T cell receptor, i.e., "a fully functional T cell receptor binding site." See, e.g., the "BACKGROUND ART" section of the specification at page 2, lines 1-23. Further, the specification provides an example of such a binding site, i.e., residues 22-90 of SPE-C. See, e.g., page 2, lines 1-8; and page 3, lines 13-19, respectively. In view of these teachings, one skilled in the art would know what is "a fully functional T cell receptor binding site of a superantigen" as recited in claim 1. One skilled in the art would also know what is "[an]... APC targeting molecule ... has little or no ability to activate T cells" as recited in claim 2 in light of the specification. Indeed, the specification describes a working example in this regard at page 16, Example 3. Thus, claims 1 and 2 both meet the meet the definiteness requirement.

III

The Examiner rejected claim 13 for indefiniteness. This claim recites "[an] immunomodulatory antigen is non-immunogenic when not coupled to the antigen presenting cell (APC) targeting molecule." The Examiner asserted that

> the term "non-immunogenic" is indefinite. It is unclear how an antigen can be both immunomodulatory (i.e., capable of positively or negatively stimulating an immune response) and also non-immunogenic (i.e., not capable of stimulating an immune response.

See the Office Action, page 3, lines 31-36.

Applicants disagree. It is well known in the art that certain antigens are themselves non-immunogenic. They can be made immunogenic by conjugating to other molecules, including the so-called carriers. Here, the "immunomodulatory antigen" recited in claim 13 is such an antigen as it is "non-immunogenic when not coupled to the antigen presenting cell (APC) targeting molecule." Further, as taught in the specification, the immunomodulatory antigen is more immunogenic once conjugated to the APC targeting molecule. See, e.g., page 6, lines 11-27. Thus, there is nothing indefinite about claim 13.

In view of the above remarks, Applicants submit that claims 1-4, 6, 10, 11, 13, and 15-16 meet the definiteness requirement. So are claims 5, 7-9, and 14, all of which depend from claim 1.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

The Examiner rejected claims 1-4, 11-13, and 15-16 for not meeting the written description requirement. See the Office Action, page 4, lines 3-12. Independent claim 1 recites "[an] APC targeting molecule mimics a superantigen." Independent claim 2 recites "[an] APC targeting molecule is a molecule which is structurally a superantigen." According to the Examiner, "Applicant[s] ha[ve] not adequately disclosed that they are in possession of APC-targeting molecules that 'mimic' a superantigen or that are 'structurally' a superantigen." See the Office Action, page 4, lines 9-12. Applicants disagree and traverse below.

Claim 2 is discussed first. Applicants note that the meaning of "[an] APC targeting molecule is a molecule which is structurally a superantigen" is well known in the art. More

specifically, it refers to a polypeptide (here, the APC targeting molecule) sharing a structural element with another polypeptide (here, the superantigen), i.e., an amino acid sequence. The specification provides both a general description and detailed working examples of APC targeting molecules that contain parts of a superantigen. See, e.g., page 3, lines 13-19 and page 7, line 15 to page 15, line 26. Thus, Applicants have "adequately disclosed that they are in possession of APC-targeting molecules ... that are 'structurally' a superantigen." In other words, claim 2 meets the written description requirement.

Applicants have amended claim 1 to replace the citation at issue with "[an] APC targeting molecule contains a part of a superantigen." For the same reasons set forth immediately above, claim 1 also meets the written description requirement. So do claims 3-11 and 13-16, all of which depend from claim 1.

In view of the above remarks, Applicants respectfully submit that the rejection has been overcome.

Rejection under 35 U.S.C. § 112, first paragraph (enablement)

The Examiner rejected claim 12 for lack of enablement. See the Office Action, page 5, lines 16-24. Applicants have canceled this claim, thereby rendering the rejection moot.

Rejection under 35 U.S.C. § 102(b)

The Examiner rejected claims 1-4, 6, 10-11, and 15-16 for being anticipated by Yamoaoka *et al.*. 1998, Infection and Immunity, vol. 66 pp 5020-5026 ("Yamoaoka"). See the Office Action, page 6, lines 28-30. Applicants disagree and discuss independent claim 1 first.

Claim 1 is drawn to an immunomodulator that contains an antigen-presenting-cell (APC) targeting molecule coupled to an immunomodulatory antigen. The APC-targeting molecule contains a part of a superantigen that does not include a fully functional T-cell receptor binding site. According to the Examiner, Yamoaoka teaches a fusion protein that includes a mutated superantigen sequence and a GST protein sequence. It is her position that these two sequences are respective equivalents to the APC targeting molecule and the immunomodulatory antigen recited in claim 1. See the Office Action, page 6, last paragraph.

Applicants would like to point out that the GST protein taught in Yamoaoka is not an immunomodulatory antigen as required in claim 1. Indeed, GST protein interferers with binding to MHC class 2 protein during antigen presentation. It is therefore not within the scope of the immunomodulatory antigen as recited in claim 1. Thus, claim 1 is novel over Yamoaoka. So are claims 3-11 and 13-16, all of which depend from claim 1.

Independent claim 2 is also drawn to an immunomodulator that contains an APC targeting molecule coupled to an immunomodulatory antigen. For the same reason set forth above, it is also novel over Yamoaoka.

CONCLUSION

Applicants submit that grounds for the objections and rejections asserted by the Examiner have been overcome, and that claims, as pending, define subject matter that is definite, sufficiently described, enabled, and novel. It is therefore submitted that allowance of this application is proper, and early favorable action is solicited. Enclosed is a $225 check for the Petition for Extension of Time fee. Please apply any other charges to deposit account 06-1050.

Respectfully submitted,

Date: 2-7-2006

Jianmng Hao, Ph.D.
Reg. No. 54,694

Fish & Richardson P.C.
Telephone: (617) 542-5070
Facsimile: (617) 542-8906

21262057.doc